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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/939,709	08/28/2001	Roland E. Baron	044574-5045-US	2739

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EXAMINER
WOITACH, JOSEPH T

ART UNIT	PAPER NUMBER
1632	15

DATE MAILED: 05/15/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

File

Office Action Summary

Application No.	Applicant(s)
09/939,709	Baron et al.
Examiner	**Art Unit**
Joseph Woitach	1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Mar 3, 2003*.

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-18, 23, 24, and 31-44* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☐ Claim(s) _____ is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☒ Claims *1-18, 23, 24, and 31-44* are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892).
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

This application filed August 28, 2001 claims benefit to provisional application 60/228,450, filed August 29, 2000.

Applicants' amendment filed March 3, 2003, paper number 14, has been received and entered. Claims 19-22, 25-30 have been canceled. Claims 31-44 have been added. Claims 1-18, 23, 24 and 31-44 are pending.

Election/Restriction

Applicant's election filed February 31, 2003, paper number 13, is noted. Upon evaluation of the newly submitted claims, in particular specific limitation not previously recited in the original claims, a new restriction requirement is being made.

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-15, drawn to a method of identifying an agent that modulates bone formation or adipogenesis comprising administering an agent and monitoring ΔFosB, classified in class 435, subclass 6.

II. Claims 16, 17, drawn to method of inducing bone formation or adipogenesis by inducing ΔFosB expression, classified in various classes depending on agent delivered for example class 514, subclass 1 (undefined organic agent); class 514,

subclass 2 (administering antibody) or class 514, subclass 44 (administering polynucleotide).

III. Claim 18, drawn to method of treating osteosclerosis by inhibiting ΔFosB expression, classified in various classes depending on agent delivered for example class 514, subclass 1 (undefined organic agent); class 514, subclass 2 (administering antibody) or class 514, subclass 44 (administering polynucleotide).

IV. Claims 23, 24, 31-44, drawn to a method of identifying genes which are modulated by ΔFosB, classified in class 536, subclass 23.1 and class 800; subclass 3.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II-IV are related as method making a product and a process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. In the instant case the methods are different and distinct requiring different method steps and materials to practice. Further, the potential products generated from the method of Group I can be used in a variety of methods as set forth in Groups II-IV. Additionally, the agents obtained from the method of Group I can be used to analyze other physiological effects of the agent or the effect on other genes other than DFosB.

Inventions II-IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to separate and distinct methods requiring different materials and method steps to practice. The methods of Group II and IV require inducing expression of ΔFosB which may require different materials to affect the first step, and additionally, they differ in the second step of what is affected wherein group II affects the physiology of a whole animal and group IV affects only gene expression in a cell with no physiological consequence, each a different method step requiring different materials to practice. The method of Group III encompasses a unique first and second step requiring first the opposite effect of Groups II and IV by inhibiting ΔFosB expression and second appraises a different physiological effect than Group II. Group V is unrelated to any of II-IV because it administers unknown genes and simply monitors ΔFosB expression with no consequence of ΔFosB expression. None of the other methods require administering test genes or monitoring ΔFosB expression, and the final step of Group V results in a materially different outcome than the other methods encompassed by Groups II-IV.

In addition, if Group IV is elected an election of species is required. This application contains claims directed to the following patentably distinct species of the claimed invention: **First**, claim 23 encompasses modulating ΔFosB (1) *in vitro* and (2) *in vivo*. Specifically, claim 31 is drawn to the method practiced *in vitro*, and claim 37 is drawn to practicing the method *in*

vivo. Applicants must elect practice of the method of either (1) *in vitro* or (2) *in vivo*. **Second**, if the species of *in vitro* methods is elected, the claims recite and encompass various specific cell types and cell lines (claims 32 and 33). If the species of *in vitro* methods is elected, Applicants must elect one specific species of cell in which the assay is performed selected from the group set forth in claims 32 and 33. Third, if the species of *in vivo* methods is elected, the claims recite and encompass practice of the method in normal and transgenic animals (claims 38 and 39). If the species of *in vivo* methods is elected, Applicants must elect one specific species of either practice in a normal animal or practice in a transgenic animal as set forth in claims 38 and 39.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 23, 36, 40-44 are generic to assaying the cell both *in vitro* and *in vivo*.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after

the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, divergent subject matter and separate search requirement, restriction for examination purposes as indicated is proper.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Woitach whose telephone number is (703)305-3732.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached at (703)305-4051.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group analyst Dianiece Jacobs whose telephone number is (703) 308-2141.

Papers related to this application may be submitted by facsimile transmission. Papers should be faxed via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center numbers are (703)308-4242 and (703)305-3014.

Joseph T. Woitach

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